



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,112	05/06/2004	Jaime Simon	3716444.00011	8566
24573 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690	7590 11/09/2010		EXAMINER SAMALA, JAGADISHWAR RAO	
			ART UNIT 1618	PAPER NUMBER
			NOTIFICATION DATE 11/09/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

### Office Action Summary

**Application No.**

10/840,112

**Applicant(s)**

SIMON ET AL.

**Examiner**

JAGADISHWAR R. SAMALA

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of Applicant's Request for Continued Examination and Arguments filed on 10/12/2010.

- Claims 1, 2, 13 and 14 have been amended.
- Claims 15-23 have been cancelled.
- Claims 1-15 are pending in the instant application.

#### **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/2010 has been entered.

#### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoki Yonekawa et al (JP H10-130154) in view of Samejima et al (EP 0077956) are withdrawn in view of amendments to claims.

However, upon further consideration a new ground(s) of rejection is prepared as follow.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samejima et al (EP-077,956) in view of Berger et al (US 4,470,975).

Claims are drawn to a method for treating a fluid overload state in a host, comprising directly delivering to the intestinal tract an effective amount of a water-soluble polymer which is capable of absorbing at least 10 times its weight in physiological saline.

Samejima teaches an enteric coated microcapsules containing an active component as core material, the coating walls of which consists essentially of ethylcellulose and an enteric polymeric material such as hydroxypropyl methylcellulose phthalate, copolymers of methacrylic acid or methacrylate (abstract and page 4 and 5). The core material includes cellulose, starch, carboxymethyl cellulose, cross-linked

dextran, cross-linked polyacrylic acid, self-cross-linked methacrylic acid, which shows at least 1.2 times increase in weight (page 6 lines 1-10). The water-swellaable polymer material incorporated into the core material in microcapsules are same polymers as recited in the instant claims and will innate to have the capacity to absorb water at least 10-40 times of its weight in physiological saline. Additional disclosure includes that the enteric coated microcapsules are capable of releasing easily the active component (core material) in intestinal tract while protecting the core material sufficiently in stomach. To make the coating the coating walls porous, by which the penetration of liquid into the core material is promoted and then the water-swellaable polymer material absorbs the liquid and swells.

Samejima fails to teach fluid overload state such as congestive heart failure, renal diseases, or edema.

Berger teaches a method of removing fluid or edema by diverting water elimination from the renal route to the gastrointestinal route, and removing excess water from the body by the gastrointestinal tract of an animal by administering to said animal a polysaccharide such as dextran (see abstract, column 1, line 54-56. and column 10, lines 5-30). The cross-linked polysaccharides are capable of absorbing water with swelling, the water regain of the product being within the range of about 1 to 50 grams per gram of the dry gel product administered (see col. 4 lines, 34-59). The method also includes treatment for diseases characterized by an abnormal excess accumulation of fluid within the body, such as, congestive heart failure, cirrhosis of liver, nephrosis, and other renal diseases associated with fluid retention (col. 1 line 63+). Additional

disclosure includes that the insoluble cross-linked polysaccharide polymer may be ingested by the patient and during passage of these substances through the digestive system, water is absorbed or bound tremendously and finally along with bound water, urea in the lumen of the gastrointestinal system is then eliminated by passage from the alimentary canal in the normal manner.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Berger's teaching into Samejima's enteric coated microcapsules. The person of ordinary skill in the art would have been motivated to make those modifications because, samejima teaches that pharmaceutical compounds which are decomposed or inactivated by gastric juice can microcapsulated by enteric coating material, thereby sufficiently protected in stomach and are rapidly released in intestinal tract, to make the coating walls porous, by which the penetration of liquid into the core material is promoted and than the water-swellaable polymer material absorbs the liquid and swells (page 12 lines 4-15). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because both Samejima and Berger teaches a composition that can be used in the same filed of endeavor, such as successfully removing excess body fluids or water by administering an effective amount of a water-soluble polymer to the host.

**Conclusion**

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./  
Examiner, Art Unit 1618

/Jake M. Vu/  
Primary Examiner, Art Unit 1618

